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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/468,145	06/06/95	ENGEL	J Y17506/93-11

EXAMINER

18M1/0916

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ART UNIT	PAPER NUMBER
1817	11

DATE MAILED: 09/16/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☑ Responsive to communication(s) filed on 6-12-97

☑ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☑ Claim(s) 9, 10, 12-19 is/are pending in the application.
Of the above, claim(s) 9, 10 is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☑ Claim(s) 12-19 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

★ U.S. GPO: 1996-421-630

DETAILED ACTION

Response to Amendment

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1817.

1. Applicants' amendment filed June 12, 1997 is acknowledged and has been entered. Claims 1-8 and 11 have been canceled. New claims 12-19 have been added. Claims 12-19 are now pending in the present application.

2. Applicant's election with traverse of Invention I, claims 1-8 and 11 (now claims 12-19) in Paper No. 10 is acknowledged. The traversal is on the ground(s) that the Groups I-III are so linked as to form a single general inventive concept and that it would not be an undue burden for the Examiner to search all of the claims. This is not found persuasive because the restriction Groups have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. A reference which would anticipate the invention of one group would not necessarily anticipate or make obvious any of the other groups. Moreover, as to the question of burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues also exist.

The requirement is still deemed proper and is therefore made FINAL.

3. This application contains claims 9 and 10 drawn to an invention non-elected with traverse in Paper No. 10. A complete response to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) MPEP § 821.01.

4. Claims 12-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2173.05(l). The omitted steps are: the claims lack a recovery step. Claims 17 and 18 are indefinite for being in improper Markush format. The Office recommends the use of the phrase "selected from the group consisting of..." with the use of the conjunction "and" rather than "or" in listing the species. See MPEP 706.03(Y). Claims 1-16 are indefinite because they contain the abbreviation "LHRH". Full terminology should be in each instance in the claims without the additional use of redundant abbreviations in parentheses or otherwise. Correction is required.

5. The rejection of claims 1-8 and 11 (now claims 12-19) under 35 U.S.C. § 103 as obvious over Callahan et al in view of Finkenaur (EP 88-308573), and further in view of Reissman et al, Moore, Yoshikawa et al, Brown et al, Stewart et al or Kornreich et al is maintained. This rejection is maintained for essentially the same reasons as the rejection of claims 1-8 and 11 under this statutory provision, as set forth in the last Office action. Applicants' arguments filed June 12, 1997, have been fully considered but they are not deemed to be persuasive.

It is noted that the claims are directed to a method of preparing a sterile lyophilizates of gel-forming peptide salts by dissolving peptide salts in acetic acid to form a solution, diluting the solution with water, adding a bulking agent, and sterile-filtering the solution, dispensing into vials and lyophilizing the solution.

Applicants have asserted that the prior art does not teach the claimed process of preparing a sterile cetrorolix lyophilisate, how to make a sterile filtrate or the use of an aqueous acetic acid solution in order to dissolve the peptide salt to avoid gel formation.

It is not understood what Applicants mean regarding the art not teaching the use of an aqueous acetic acid solution in order to dissolve the peptide salt to *avoid* gel formation, when the claims recite "preparation of sterile lyophilizates of gel-forming peptide salts..."

As set forth in the previous Office Action, the prior art teaches the lyophilization of a peptide in the presence of acetic acid and a bulking agent (mannitol) as well as the peptide claimed for use in a pharmaceutical composition. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to sterilize the peptide salts as they are to be used in a pharmaceutical composition for administration to a mammal.

It is not understood what Applicants mean, at page 6 of the Response, by "USP 23/NI-18 Pages 1650, 1997, 1978. If this is a reference Applicants are relying on to show that the 103 prior art references are not enabled or that they are not appropriate prior art, Applicants are requested to provide a copy of this reference so that the Examiner may properly consider said reference.

6. No claims are allowed.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is (703) 305-3394. The examiner can normally be reached on Monday-Thursday from 7:00 AM-4:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula K. Hutzell, Ph.D., can be reached on (703) 308-4310. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

N. M. Minnifield
September 4, 1997

NITA M. MINNIFIELD
PRIMARY PATENT EXAMINER
GROUP 1800